

REQUEST FOR RECONSIDERATION

Claims 1-5 and 11-29 remain active in this application.

The claimed invention is directed to a method of treating hair.

Improvements in hair feel and stylability are generally sought. Conventional methods of applying hair treatments to shampooed **wet hair** are not always entirely effective. Effective methods would be welcome.

The present invention addresses this issue by providing a method of conditioning hair by applying a hair treatment composition **consisting essentially of** 0.5 to 25 % by weight of at least one oil agent, a solvent, and having a water content of 0 to 15 % by weight **to dry hair**, letting stand, then **washing away** after letting stand. Such a composition relates to a method of imparting improved feel and stylability or manageability to hair (pg 1, lines 2-3). Applicants have discovered that such a method is effective in conditioning hair. Such a method is nowhere disclosed in the cited prior art of record.

The rejection of claims 1-5 and 11-29 under 35 U.S.C. 112, second paragraph is respectfully traversed.

The term “consisting essentially of” limits the scope of the claim to the specified materials and those that do not materially affect the basic and novel characteristic of the claimed invention (MPEP 211.03). The invention is directed to a method of treating hair for improving feel or stylability or manageability (page 1, lines 22-24 of applicants’ specification). Accordingly, the basis and novel characteristics of the composition used in the claimed method is clear in so far as the object of the method is to improve the feel and stylability or manageability of hair.

At the heart of the examiner's position appears to be the erroneous belief that the basic and novel characteristics of a composition must necessarily be altered by the majority, by weight, components.

There is no requirement that a claim which recites "consisting essentially of" define a majority by weight of the components. To the contrary, such a claim is interpreted based on the presence or absence of components which would affect the basic and novel characteristics of the composition.

For example, U.S. 6,906,047 claims

"an aqueous *pharmaceutical composition consisting essentially of*:

- (a) between 40 mM and 400 mM ifosfamide;
- (b) between 10 mM and 260 mM of a buffer; and
- (c) water;

wherein the molar ratio of ifosfamide to buffer is in the range of about 0.5:1 to about 20:1.

Such a claim would allow for the majority, by weight, to be other than the ifosfamide, buffer and water, yet still such a claim is viewed as definite within the meaning of 35 U.S.C. 112 §, second paragraph.

Claim 23 of 6,897,239 reads as follows:

23. A method for treating sexual dysfunction in a female subject comprising: providing a vasoactive formulation *consisting essentially of* misoprostol and/or misoprostol acid; and topically administering the formulation to the clitoris or vagina of the subject for treating sexual dysfunction by stimulating vasodilation.

Such a claim would allow for the majority, by weight, to be other than misoprostol and/or misoprostol acid, yet still such a claim is viewed as definite within the meaning of 35 U.S.C. 112 §, second paragraph.

U.S. 6,893,662 claims

A *pharmaceutical composition* in a solid unit dosage form for oral administration in a human or lower animal *consisting essentially of*:

- a. a safe and effective amount of a therapeutically active agent;

- b. an inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:2, poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures thereof; and
- c. an outer coating layer, applied to the inner coating layer, said outer coating layer comprising an enteric polymer that begins to dissolve in an aqueous medium at a pH of less than about 7, said enteric polymer being selected from the group consisting of polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof; wherein the inner coating layer is not the same as the outer coating layer; wherein if the inner coating layer is poly(methacrylic acid, methyl methacrylate) 1:1 then the outer coating layer is not poly(methacrylic acid, methyl methacrylate) 1:2 or is not a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2; and wherein the inner coating layer and the outer coating layer contain no therapeutically active agent.

Such a claim would allow for the majority, by weight, to be other than the therapeutically active agent, inner coating and outer coating, yet still such a claim is viewed as definite within the meaning of 35 U.S.C. 112 §, second paragraph.

Accordingly the present USPTO practice appears to contradict the examiner's view that claims which recite "consisting essentially of" must define a majority by weight of the composition in order to be definite within the meaning of the statute. The metes and bounds of the present invention are clear to those of ordinary skill in the art. Withdrawal of the rejection under 35 U.S.C. 112 §, second paragraph is respectfully requested.

The rejection of claims 1, 11-13, 15, 20-21, 23 and 28 under 35 U.S.C. § 102(b) over Matsunaga et al. U.S. 4,495,173 is respectfully traversed.

Matsunaga et al. fail to describe a hair treatment method in which a composition consisting essentially of 0.5-25 wt. % of at least one oil agent, a solvent and 0-15 wt. % of water is used.

Matsunaga et al. describes a pre-shampoo type hair treatment comprising decomposition derivatives of keratin material and cationic polymer (column 1, lines 7-10). The composition is prepared by **dissolving or suspending** the decomposition derivative of

keratin material, cationic polymer, and other known components, in a medium such as **water** (column 8, lines 29-39). As noted by the examiner, various formulations are illustrated, identifying specific quantities of oil agent and solvent, however it is noted that in no case is the identity of more than 13.5 wt. % of the formulation provided. There is no disclosure of an amount of water of from 0-15 wt. %. Quite to the contrary, the specification describes the preparation of the composition by dissolving or suspending in **water**. There is no suggestion to limit the amount of water in the composition and therefore no suggestion of the claim limitation of 0-15 wt. % of water. While the examiner argues the absence of description of the remaining 86.5% mass of the compositions of the reference would allow one to “envisage” alternate embodiments in which the water content was 0-15 wt. %, such is not the standard of obviousness since there is no suggestion in the reference to limit the amount of water to 0-15 wt.%. In the absence of such motivation the claimed invention can not be viewed as obvious in view of the cited reference.

In contrast, the claimed method is practiced with a composition containing only 0 to 15 wt. % of water. This is a claim limitation which is simply not disclosed or suggested in the reference. Moreover the rejection fails to identify how this claim limitation is met by the reference. As the reference fails to describe the claim limitation of an amount of water of from 0 to 15 wt. % and to the contrary describes preparation of the composition as a solution or suspension in water, the claimed invention is clearly neither anticipated nor made obvious by this reference. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

The rejection of claims 1, 11-15, 23 and 28 under 35 U.S.C. 102(b) over Ona et al. U.S. 4,450,152, is respectfully traversed.

Ona et al. fail to disclose or suggest a method in which a composition as claimed is applied to dry hair, allowed to stand 3-120 minutes, then washed away.

Ona et al. describes a hair grooming agent which is applied to hair providing excellent glossiness, suppleness, smoothness and moist feeling, the effect being durable (column 1, lines 64 through column 2, line 2). There is no description of a method in which the a composition is applied to dry hair, allowed to stand 3-120 minutes, then washed away. While the examiner cites to testing example 2 as disclosing steps of applying and washing, such a durability demonstration does not suggest **a method of conditioning hair** in which the composition is applied to dry hair, allowed to stand 3 to 120 minutes, then washed away.

Moreover, the reference example fails to identify a time period of 3-120 minutes between removal of the sample from the hair grooming agent and the time the hair sample was washed to remove the hair treatment composition. As such the reference fails to identify the claim limitation of allowing to hair to stand for 3-120 minutes and washing the hair treatment away. In view of these deficiencies, withdrawal of this ground of rejection is respectfully requested.

The rejections of claims 1, 3 and 11-27 under 35 U.S.C. 103(a) over Komori et al. U.S. 5,342,611 alone, and in view of Okumura et al. U.S. 4,402,936 and of claims 2, and 4-5 under 35 U.S.C. 103(a) over Komori et al. U.S. 5,342,611 alone, and in view of Okumura et al. U.S. 4,402,936 and further view of Priest et al. U.S. 4,296,763 are respectfully traversed.

A hair conditioning method in which the hair treatment composition consists essentially of 0.5 to 25 % by weight of at least one oil agent, a solvent, **and** having a water content of 0 to 15 % by weight, is nowhere disclosed or suggested in the cited references.

Komori et al. has been cited by the examiner as describing a hair treatment composition as claimed. This reference describes a hair **cleansing** composition comprising (a) a surfactant, (b) an alcohol, (c) 0.1 to 25 % of water, and (d) 20 to 98 wt.% of a liquid oil (see abstract). The reference describes that the claimed composition may be used in methods as diverse as shampoo, a preshampoo, a hair-make remover, a dandruff remover (column 5, lines 13-15) and

exemplifies these compositions as well as a hair cleanser and a point-set remover. There is no suggestion in the reference to use a composition which meets each of the claim limitations of 1) 0.5 to 25 % by weight of at least one oil agent and 2) a water content of 0 to 15 % by weight, at the same time, **in a method of conditioning hair by applying to dry hair.**

Applicants note that the reference describes use of the disclosed hair cleaning composition for a variety of uses, such as a shampoo, a preshampoo, a hair-make remover, a dandruff remover, a hair cleanser and a point-set remover. Many these methods do not suggest applying the composition to condition hair by applying to dry hair. The examiner has **only** identified the use of a preshampoo as suggestive of the claimed method in which the composition is applied to dry hair (page 5, line 7-8 of outstanding official action). Accordingly, only the use of the reference composition as a preshampoo is asserted as making the claimed method obvious.

However, the reference does not suggest using a preshampoo composition which contains 0.5 to 25 % by weight of at least one oil agent and a water content of 0 to 15 % by weight. For example the reference identifies a number of compositions, for specific purposes. Example 1 is identified as a hair cleaner. Examples 2 and 8 are identified as hair-make removers. Examples 3 and 9 are identified as point-set removers. Examples 4 and 10 are identified as dandruff removers. Examples 5 and 11 are identified as preshampoos. Examples 6, 7 and 12 are identified as shampoos. In no instance is any single composition identified as suitable for all of the asserted uses. To the contrary, the reference suggests specific compositions as only suitable for specific uses.

In the only compositions asserted by the examiner as suggestive of the claimed method (the preshampoos of examples 5, 11(a) and (b)), the compositions contain at least 85 wt. % of oil and 8.0 wt. % of water (example 5), 20 wt. % oil and 50 wt. % water (example 11(a)); and 18.5 wt.% oil and 45 wt. % water (example 11(b)). Accordingly, when the amount of water is

less than 15 wt. %, the amount of oil exceeds the claimed 25 wt. % maximum. Conversely, when the amount of oil is within the claimed 0.5 to 25 wt. % range, the water level exceeds the maximum claimed amount of 15 wt. %. For the preshampoo compositions described in the reference, there is a **very specific teaching** of having at least an amount oil in excess of 25 wt. % or an amount of water in excess of 15 wt. %. Accordingly there is no suggestion of a preshampoo composition having both 0.5 to 25 wt. % of an oil and 0 to 15 wt. % of water.

The basic deficiencies of the primary references are not cured by any of the remaining references of Okumura et al., Priest et al. or Hulett et al.

Okumura et al. has been cited by the examiner as describing the conventional use of a preshampoo by applying an oil containing composition to dry hair for five minutes followed by washing. Applicants note that Okumura et al. clearly identifies the conventional use of a preshampoo composition which contains **more than 15 wt. % water**. At column 3, lines 53-55 of the reference, is a disclosure that the balance of the composition is water. Each of the examples identify the amount of water as being “balance” or 96 wt. %. In the compositions in which water is “balance” no more than 24 wt. % of other components are identified, making clear that an amount of **water in excess of 15 wt %** is disclosed.

As Komori et al. does not describe limitation of the amount of water to 15 wt. % or less and having the amount of oil from 0.5 to 25 wt. % **in a preshampoo composition** and the exemplary reference cited by the examiner as the conventional use of a preshampoo composition contains an amount of water far in excess of the claimed 15wt. % maximum, the claimed method in which a composition consisting essentially of 0.5 to 25 wt. % of oil, a solvent and 0 to 15 wt. % of water is applied to dry hair is simply not suggested.

Priest et al and Hulett et al. have been cited by the examiner for their teaching of the use of a covering in a hair treatment method. However, neither of these references suggests the claimed hair treatment composition consisting essentially of 0.5 to 25 wt. % of oil, a solvent

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and 0 to 15 wt. % of water. Therefore, these additional references fail to render the claimed invention obvious.

For this reason, the claimed invention would not have been obvious from these references. Withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

The rejection of claims 1-5, 11-5, 19, 23 and 28-29 under 35 U.S.C. 103(a) over Namba et al U.S. 5,286,476 in view of Andersin GB 824,353, in further view of Priest et al. is respectfully traversed.

Nowhere is the cited references is it suggested to apply a composition consisting essentially of 0.5 to 25 wt. % of oil, a solvent and 0-15 wt.% of water, to dry hair followed by washing away the hair treatment composition.

Namba et al describes a hair cosmetic composition which imparts a smooth feeling to hair, has an excellent effect at **preventing** the generation of split hair and torn hair and repairs split ends (column 2, lines 5-9). The composition is applied to hair and remains thereon in order to provide the preventive effects of generating split ends. This is explicit from the evaluation test in which the composition is applied to hair, and subjected to brushing to measure the prevention of forming split ends (column 12, lines 54-63). The fact that this composition is to be left in the hair is implied by the presence of U.V. absorbers in the composition, to protect the hair (column 7, lines 38-46). If there were motivation to wash the composition out of the hair, there would be no reason to include a U.V. absorber. There is no washing step suggested.

The examiner cites to Andersin asserting that this reference describes the conventional use of hair oil in which the composition is applied to hair and washed away. However the composition of Andersin is much different from that of the compositions of Namba et al. such that the explicit teaching of Namba et al to leave the hair cosmetic composition in the hair can not be ignored. Quite simply to wash away the hair cosmetic composition of Namba et al would

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not be obvious as to do so would destroy the operability of the reference. The composition of Namba et al must be left on the hair in order to provide the benefits as described. To wash away the composition would not be obvious.

"Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so."(In re Fritch 23 USPQ2d 1780 1783 (Fed. Cir. (1992))).

The lack of relevancy of Priest et al. as it applies to the present rejection is made clear by applicants argument made in the prior rejection in which Priest et al was applied. The reference does not suggest a washing out step for the composition of Namba et al. Withdrawal of the rejections under 35 U.S.C. 103(a) is respectfully requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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